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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,639	08/20/2003	Xiao-Zhuo Michelle Wang	A32815-I -I - 072667.0190	7944
7590 03/16/2006			EXAMINER	
BAKER BOTTS L.L.P. 44 TH FLOOR 30 ROCKEFELLER PLAZA NEW YORK, NY 10112-0228			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,639

Applicant(s)

WANG ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,26,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25,26,28 and 29 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

- 1) Claims 23, 25, 26, 28 and 29 are pending in the instant application.

Claims 23, 26 and 29 have been amended and claims 1 to 22, 24, 27 and 30 to 37 have been canceled as requested by Applicant in the correspondence filed 20 December of 2005.

- 2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- 4) The information disclosure statement filed 20 August of 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. That statement expressly stated therein that "[c]opies of the cited references are enclosed". They were not. Applicants note that the references identified in the information disclosure statement were submitted in U.S. Patent Application Serial No. 09/969,844, now U.S. Patent No. 6,780,601, to which the present application claims priority. Therefore, it is not required for the references to be resubmitted in the present application, pursuant to C.F.R. 1.98(d)(2). Applicant is advised that 37 C.F.R. 1.98(d) states that "[a] copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent,

publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless:

- (1) The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120".

The information disclosure statement filed 20 August of 2003 does not appear to properly identify an earlier application as required by 37 C.F.R. 1.98(d) and, as indicated above, expressly stated therein that "[c]opies of the cited references are enclosed".

5) The disclosure stands objected to because it contains an embedded hyperlink and/or other form of browser-executable code.in line 10 on page 5 and line 11 on page 25. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p). Applicant has traversed this objection on the premise that "the hyperlink cited on page 5, line 10 is not intended to be incorporated by reference, and the contents of the site to which the hyperlink is directed is not intended to be incorporated into the specification". It is clear that the text "[s]equence identity is determined using the program Clustal W described by Higgins et al. (1994) Nucleic Acids Res. 22:4673 and maybe calculated using the EMBLNucleotide Sequence Database (<http://www.ebi.ac.uk/embl.html>)" is intending to impermissibly incorporate the content of the sited referred to therein by reference.

Correction is required.

6) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete

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view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 4 of the instant application, for example, is presented on two separate panels. The two sheets of drawings corresponding to "Figure 4" in the instant specification should be renumbered as Figures 4A and 4B. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

7) Claims 23, 25, 27 and 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement essentially for those reasons of record in section 7 of the previous office action. The instant claims are drawn to an assay that measures the binding to, or modulation of, a lepidopterin glutamate-gated chloride channel "wherein said lepidopteran glutamate-gated chloride channel is at least 90% homologous to the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO: 13". As stated in the original rejection, a glutamate-gated chloride channel of the instant invention is a member of a protein family known as ligand-gated ion channels (a.k.a. ionotropic receptors). As illustrated by the section entitled "The Structure of Ligand-Gated Ion Channels" and Figure 2 of the Nakanishi publication (SCIENCE 258:597-603, 23 Oct. 1992), each and every member of this protein family functions as either a homo- or hetero- pentameric transmembrane structure that forms an ion channel within a biological membrane. The amino acid sequence presented in SEQ ID NO;14 of the instant application **does not correspond**

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to a glutamate-gated chloride channel. That sequence is the amino acid sequence of a **subunit** of a glutamate-gated chloride channel that is capable of functioning as a homo-pentameric structure composed of five identical subunits. Therefore, the instant specification does not disclose a method of making a chloride channel comprising SEQ ID NO:14, it discloses a method of making a chloride channel that is composed of subunits comprising SEQ ID NO:14.

8) Claims 23, 26 and 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record as applied to claims 23, 24, 26, 27, and 29 in section 8 of the previous office action. As stated therein whereas these claims encompass a method that could employ any one of potentially thousands or tens of thousands of protein complexes encompassed by the limitation "lepidopteran glutamate-gated chloride channel" "at least 90% homologous to the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO: 13" the instant specification does not adequately describe a lepidopteran glutamate-gated chloride channel having anything other than the entire amino acid sequence presented in SEQ ID NO:14 of the instant application. Applicant's traversal of the instant rejection on the premise that "a person of ordinary skill in the art would be capable of identifying other chloride channels with the requisite level of homology without undue experimentation." To the contrary, one of ordinary skill would recognize that the majority of protein embodiments meeting the limitation of "is at least 90% homologous to the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO:13" are synthetic proteins and

not "lepidopteran" in origin. As stated in the original rejection, *in re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

" It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary."

In the instant case, the specification only describes a single species of the claimed genus and this single species hardly constitutes a representative number of species within the genus of molecules encompassed by the limitations recited in the instant claims.

9) Claims 23, 25, 26, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9.1) Claims 23, 25, 26 and 28 are vague and indefinite because the limitation "wherein said lepidopteran glutamate-gated chloride channel is at least 90% homologous to the sequence..." is illogical. In the art of molecular biology the term "homology" refers to similarities between **analogous features** from different entities. Therefore, the instant claims should be referring to "the amino acid sequence of said

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lepidopteran glutamate-gated chloride channel" when referring to the similarity between two different amino acid sequences.

9.2) Claims 23, 25, 26, 28 and 29 are confusing because it is unclear how the limitation "the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO:13" differs materially from the limitation "the amino acid sequence of SEQ ID NO: 14". If "the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO:13" is not identical to "the amino acid sequence of SEQ ID NO: 14" then Applicant needs to explain how these limitations materially differ from one another.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to be 'J. Ulm', written in a cursive style.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800